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TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION

PART 335
MEDICAL USE OF RADIOACTIVE MATERIAL

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335.APPENDIX A List of Specialty Board Certifications Recognized by the Agency Until October 24, 2007 (Repealed)

AUTHORITY: Implementing and authorized by Section 10 of the Radiation Protection Act of 1990 [420 ILCS 40/10].

SOURCE: Adopted at 15 Ill. Reg. 10763, effective July 15, 1991; emergency amendment at 17 Ill. Reg. 9099, effective June 8, 1993, for a maximum of 150 days; amended at 18 Ill. Reg. 7308, effective May 2, 1994; emergency amendment at 26 Ill. Reg. 4434, effective March 8, 2002, for a maximum of 150 days; amended at 26 Ill. Reg. 10517, effective July 1, 2002; amended at 27 Ill. Reg. 10057, effective June 30, 2003; recodified from the Department of Nuclear Safety to the Illinois Emergency Management Agency at 27 Ill. Reg. 13641; amended at 30 Ill. Reg. 9029, effective April 28, 2006; amended at 32 Ill. Reg. 9247, effective June 13, 2008; amended at 35 Ill. Reg. 884, effective December 30, 2010; amended at 37 Ill. Reg. 12406, effective July 19, 2013; amended at 45 Ill. Reg._____, effective _____.

SUBPART A: GENERAL INFORMATION

Section 335.20 Definitions

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using or storing radioactive material.

"Associate Radiation Safety Officer" means an individual who, for this Part only, meets the requirements in Sections 335.9010 and 335.9180 and is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on a specific medical use license issued by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State or on medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

"Authorized user" means a physician, dentist or podiatrist who meets the requirements in Subpart J ~~of this Part~~ or is identified as being authorized to use radioactive material on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State ~~or a Licensing State~~; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by a U.S. Nuclear Regulatory Commission or~~,~~ Agreement State ~~or Licensing State~~ broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

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"Authorized medical physicist" means an individual who meets the requirements in Sections 335.9150(a) and 335.9180 ~~of this Part~~; or is identified as an authorized medical physicist or teletherapy physicist on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or~~,~~ an Agreement State ~~or Licensing State~~, a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an~~,~~ Agreement State ~~or Licensing State~~ broad scope medical use licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

"Case" means the performance of a clinical procedure on a patient.

"Classroom and laboratory training" means planned instruction outlined in a syllabus and offered by an individual or organization. It is comprised of lectures, demonstrations, hands-on laboratory exercises and tests.

"Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with Section 335.2120 ~~of this Part~~.

"Clinical procedure" means a method of using radioactive material for patient care in which the material or its radiation is administered to the patient. A specific clinical procedure specifies, either explicitly or in context, the indication for the procedure, the purpose (diagnosis or therapy), the radionuclide and its chemical and physical form, the dosage or dose and method of administration and patient follow-up. Diagnostic clinical procedures also include the method of collecting raw data, manipulating the data and interpreting the final results, which may be images, graphs or numbers.

"Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice dentistry.

"Gamma stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

"High dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Intravascular brachytherapy" means a type of brachytherapy in which the brachytherapy sources are placed into blood vessels at the point where the dose is prescribed for the treatment of in-stent restenosis.

"Low dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

"Management" means the chief executive officer or other individual having the authority to manage or administer the licensee's activities, or those individuals' delegates.

"Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"Medical event" means an event that meets the criteria in Section 335.1080 ~~of this Part~~.

"Medical institution" means:

An organization, other than a medical clinic, private medical practice or mobile nuclear medicine service, that holds a specific license issued by the Agency and that practices more than two medical disciplines; or

A medical clinic, private practice or mobile nuclear medicine service that holds a specific license issued by the Agency and is authorized under Section 335.2140, 335.5010 (for therapy procedures only), 335.7010 or 335.8010 ~~of this Part~~ to use radioactive material.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Medium dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Mobile medical service" means the transportation of radioactive material to, and its medical use at, the client's address.

"Ophthalmic physicist" means an individual who meets the requirements in Sections 335.7100(b) and 335.9180; and is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

"Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"Physically present" means within audible range and in such proximity that immediate assistance can be given if required.

"Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice podiatry.

"Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~or~~ a Radiation Safety Officer, or an Associate Radiation Safety Officer.

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

in a written directive; or

in accordance with the directions of the authorized user for procedures pursuant to Sections 335.3010 and 335.4010 ~~of this Part~~.

"Prescribed dose" means:

for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

for teletherapy, the total dose and dose per fraction as documented in the written directive;

for manual brachytherapy and intravascular brachytherapy, either the total dose or the total source strength and exposure time, as documented in the written directive; or

for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Pulsed dose rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose rate" range, and:

is approximately one-tenth of the activity of typical high dose rate remote afterloader sources; and

is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

"Radiation Safety Officer" means an individual who:

meets the requirements in Sections 335.9010~~, 335.9160~~ and 335.9180 ~~of this Part~~; or

is identified as a Radiation Safety Officer on:

a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State ~~or a Licensing State~~; or

a medical use permit issued by a U.S. Nuclear Regulatory ~~the Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State broad scope licensee or master material license permit or by a master material license permittee of broad scope~~ Commission master material licensee.

"Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

"Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Type of use" means use of radioactive material under Section 335.2140, 335.3010, 335.4010, 335.5010, 335.6010, 335.7010 or 335.8010 ~~of this Part~~.
"Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Visiting authorized user" means a temporary (i.e., less than 60 days each year) authorized user who is not identified on the license of the licensee being visited and who has been approved by the Radiation Safety Committee in accordance with Section 335.1060(b) ~~of this Part~~.

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Section 335.1110 ~~of this Part~~.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.35 Suppliers for Sealed Sources or Devices for Medical Use

For medical use, a licensee shall only use:

a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 32 Ill. Adm. Code 330 or equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State;

b) Sealed sources or devices non-commercially transferred from an Agency, U.S. Nuclear Regulatory Commission or an Agreement State medical use licensee.

c) Teletherapy sources manufactured and distributed in accordance with a license issued under 32 Ill. Adm. Code 330 or equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State.

Section 335.40 License Amendments

For specific licenses issued pursuant to 32 Ill. Adm. Code 330.260(a) or 330.260(b), a licensee's management shall apply for and shall receive a license amendment:

a) Before using radioactive material for any use not permitted by the license;

b) Before permitting anyone~~, except a visiting authorized user described in Section 335.1060 of this Part,~~ to work as an authorized user, authorized medical physicist, or ophthalmic physicist under the license, except: ~~under the license;~~

1) For a visiting authorized user, as described in Section 335.1060;

2) For an authorized user, an individual who meets:

A) The requirements in 335.9180; and

B) The applicable board certification requirements in subsections 335.9030(a), 335.9040(a), 335.9050(a), 335.9060(a), 335.9070(a), 335.9100(a), 335.9130(a), and 335.9140(a);

3) For an authorized medical physicist, an individual who meets the requirements in subsection 335.9150(a) and Section 335.9180;

4) An individual who is identified as an authorized user, an authorized medical physicist, or an ophthalmic physicist on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license or other equivalent permit recognized by the Agency that authorizes the use of byproduct material in medical use, on a permit issued by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use, or on a permit issued by the U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the use of byproduct material in medical use;

c) Before changing the Radiation Safety Officer, except as provided in subsection 335.1040(c) ~~or authorized medical physicist. If the authorized medical physicist named on the license is no longer performing his or her duties, the Radiation Safety Committee may have the duties performed by an individual who is listed~~

~~by name as an authorized medical physicist on an Agency, U.S. Nuclear Regulatory Commission, Agreement State or Licensing State license, and who meets the training criteria listed in Section 335.9150 of this Part, for up to 90 days while an amendment is being obtained~~;

d) Before permitting anyone to work as an Associate Radiation Safety Officer or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

e~~d~~) Before receiving radioactive material in excess of the amount, in a different form, or a different radionuclide than is authorized on the license;

f~~e~~) Before adding to or changing any area of use identified on the license, including changing the shielding in any area approved on the license. This includes areas used in accordance with Section 335.3010 or 335.4010 if the change includes addition or relocation of an area where PET radionuclides are used, administered, produced, or stored. Other areas of use where radioactive material is used only in accordance with either Section 335.3010 or 335.4010 are exempt;

g) Before changing the addresses of use identified in the license;

h~~f~~) Before changing statements, representations and procedures that are incorporated into the license; ~~and~~

~~g) Within 30 days after a Radiation Safety Officer or authorized medical physicist permanently discontinues performance of duties under the license, or after changing the name or the mailing address of the licensee as it appears on the license.~~

i) Before receiving a sealed source from a different manufacturer or of a different model number than authorized by the license, unless the sealed source is used for manual brachytherapy, listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.45 Notifications

a) For specific licenses issued pursuant to 32 Ill. Adm. Code 330.260(a) or (b), a licensee shall provide the Agency, no later than 30 days after the date that the licensee permits an individual to work under the provisions of subsection

335.40(b) as an authorized user, authorized medical physicist, or ophthalmic physicist:

1) A copy of the board certification and, as appropriate, verification of completion of:

A) Training for the authorized medical physicist under subsection 335.9150(d);

B) Any additional case experience required in subsection 335.9050(b)(2)(F) for an authorized user under Section 335.5010; or

C) Device specific training in subsection 335.9140(d) for the authorized user under Section 335.8010; or

2) A copy of the Agency, U.S. Nuclear Regulatory Commission or Agreement State license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by the Agency, U.S. Nuclear Regulatory Commission or Agreement State licensee of broad scope, or the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee for each individual whom the licensee permits to work under the provisions of this Part.

b) A licensee shall notify the Agency no later than 30 days after:

1) An authorized user, Radiation Safety Officer, Associate Radiation Safety Officer, authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

2) The licensee permits an individual qualified to be a Radiation Safety Officer under Sections 335.9010 and 335.9180 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with subsection 335.1040(c);

3) The licensee's mailing address changes;

4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 32 Ill. Adm. Code 330.310(c);

5) The licensee has added to or changed the areas of use identified in the license where byproduct material is used in accordance with either Section 335.3010 or 335.4010 if the change does not include an area where PET radionuclides are used, administered, produced, or stored; or

6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in subsection 335.40(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(Source: Added at 45 Ill. Reg. _____, effective _____)

SUBPART B: GENERAL ADMINISTRATIVE REQUIREMENTS

Section 335.1040 Authorities and Responsibilities for the Radiation Protection Program

a) In addition to the radiation protection program requirements of 32 Ill. Adm. Code 340.110, a licensee's management shall approve in writing:

1) Requests for a license application, renewal or amendment before submittal to the Agency.

2) Any individual before allowing that individual to work as an authorized user or authorized medical physicist.

b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, shall assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

c) For up to 60 days each year, a~~A~~ licensee may permit an ~~authorized user or an~~ individual qualified to be a Radiation Safety Officer, under Sections 335.9010 and

335.9180~~, 335.9160, 335.9180 and 335.9190 of this Part~~, to function as a temporary Radiation Safety Officer ~~designee~~ and to perform the functions of a Radiation Safety Officer, as provided in subsection (g)~~ of this Section~~, if the licensee takes the actions required in subsections (b), (e), (g), (h) and (i)~~ of this Section~~. The licensee shall provide notification to the Agency in accordance with subsection 335.45(b).

d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with subsection (c)~~ of this Section~~, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of radioactive material permitted by the license.

e) A licensee shall establish the authority, duties and responsibilities of the Radiation Safety Officer in writing.

f) Licensees that are authorized for two or more different types of uses of radioactive material under Subparts ~~E,~~ F, H and I or Section 335.2140~~ of this Part~~ for emerging technologies, or two or more types of units under Subpart I~~ of this Part~~, shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources and management prerogative to:

1) Identify radiation safety problems;

2) Initiate, recommend or provide corrective actions;

3) Stop unsafe operations; and

4) Verify implementation of corrective actions.

h) A licensee shall retain a record of actions taken by the licensee's management in accordance with subsection (a)~~ of this Section~~ for 5 years. The record shall include a summary of the actions taken and a signature of licensee's management.

i) The licensee shall retain a copy of the authority, duties and responsibilities of the Radiation Safety Officer as required by subsection (e)~~ of this Section~~ and a signed

copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by subsection (b) ~~of this Section~~, for the duration of the license. The records shall include the signature of the Radiation Safety Officer and licensee's management.

j) For each Associate Radiation Safety Officer appointed under subsection (b), the licensee shall retain a copy of the written document appointing the Associate Radiation Safety Officer, signed by the licensee's management, for 5 years after the Associate Radiation Safety Officer is removed from the license.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.1060 Authorized User and Visiting Authorized User

a) A licensee shall assure that only authorized users of radioactive material:

1) Select or establish written criteria for the selection of the patients to receive radioactive material or radiation therefrom; and

2) Prescribe the radiopharmaceutical dosage or radiation dose to be administered.~~; and~~

~~3) Interpret the results of tests, studies, or treatments.~~

b) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for up to 60 days each year without applying for a license amendment if:

1) The physician is licensed in accordance with the Medical Practice Act of 1987;

2) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

3) The licensee has a copy of a license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that identifies the visiting authorized user by name as an authorized user; and

4) The visiting authorized user performs only those procedures for which the visiting authorized user is specifically authorized by a license described in subsection (b)(3) ~~of this Section~~.

c) A licensee shall retain copies of the records specified in subsection (b) ~~of this Section~~ for 5 years.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.1080 Report and Notification of a Medical Event

a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which ~~the administration of radioactive material or radiation from radioactive material results in~~:

1) The administration of a radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

A)~~1)~~ A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

i~~A~~) The total dose delivered differs from the prescribed dose by 20 percent or more;

ii~~B~~) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

iii~~C~~) The fractionated dose delivered differs from the prescribed dose~~,~~ for a single fraction, by 50 percent or more.

B~~2~~) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

i~~A~~) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

ii~~B~~) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

iii~~C~~) An administration of a dose or dosage to the wrong individual or human research subject;

ivD) An administration of a dose or dosage delivered by the wrong mode of treatment; or

vE) A leaking sealed source.

C3) A dose to the skin or an organ or tissue other than the treatment site that exceeds: ~~by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

i) By 0.5 Sv (50rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

ii) By 50 percent or more of the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

A) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

B) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

C) An administration that includes any of the following:

i) The wrong radionuclide;

ii) The wrong individual or human research subject;

iii) Sealed sources implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

iv) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

c) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.

d) By an appropriate method listed in 32 Ill. Adm. Code 310.110, the~~The~~ licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

1) The written report shall include:

A) The licensee's name;

B) The name of the prescribing physician;

C) A brief description of the event;

D) Why the event occurred;

E) The effect, if any, on the individual who received the administration;

F) What actions, if any, have been taken or are planned to prevent recurrence; and

G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, why not.

2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24

hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f) Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to those individuals' responsible relatives or guardians.

g) A licensee shall:

1) Annotate a copy of the report provided to the Agency with the:

A) Name of the individual who is the subject of the event; and

B) Identification number, or if no other identification number is available the social~~Social~~ security number ~~or other identification number, if one has been assigned~~, of the individual who is the subject of the event; and

2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

h) A licensee shall report to the Agency immediately upon discovery of any irregularities pertaining to identification, labeling, quality or assay of any radiopharmaceutical received under the authority of the license.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.1100 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

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a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

b) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

c) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (a) or (b) ~~of this Section~~.

d) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (a) or (b) ~~of this Section~~.

1) The written report shall include:

A) The licensee's name;
B) The name of the prescribing physician;

C) A brief description of the event;

D) Why the event occurred;

E) The effect, if any, on the embryo/fetus or the nursing child;

F) What actions, if any, have been taken or are planned to prevent recurrence; and

G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, why not.

2) The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subsection (a) or (b) ~~of this Section~~, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection (e), the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide a written description if requested.

f) A licensee shall:

1) Annotate a copy of the report provided to the Agency with the:

A) Name of the pregnant individual or the nursing child who is the subject of the event; and

B) Identification number, or if no other identification number is available the social~~Social~~ security number ~~or other identification number, if one has been assigned~~, of the ~~pregnant~~ individual ~~or the nursing child~~ who is the subject of the event; and

2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.1110 Written Directives

a) A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information

contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours after the oral directive.

b) The written directive shall contain the patient's or human research subject's name and the following information:

1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131, the dosage.

2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131, the radioactive drug, dosage and route of administration.

3) For gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.

4) For teletherapy, the total dose, dose per fraction, number of fractions and treatment site.

5) For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions and total dose.

6) For permanent implant brachytherapy:

A) Before implantation: the treatment site, the radionuclide, and the total source strength; and

B) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

7~~6~~) For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:

A) Before implantation:~~,~~ treatment site, the radionuclide and dose; and

B) After implantation but before completion of the procedure:~~,~~ the radionuclide, treatment site, number of sources, ~~and~~ total source strength, and exposure time (or the total dose) and date.

c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours after the oral revision.

d) A licensee shall retain a copy of each written directive as required by subsections (a) and (c) ~~of this Section~~ for 5 years.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.1120 Procedures for Administrations Requiring a Written Directive

a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1) The patient's or human research subject's identity is verified before each administration; and

2) Each administration is in accordance with the written directive.

b) At a minimum, the procedures required by subsection (a) ~~of this Section~~ shall address the following items that are applicable to the licensee's use of radioactive material:

1) Verifying the identity of the patient or human research subject;

2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

3) Checking both manual and computer-generated dose calculations; ~~and~~

4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 335.2140 or 335.8010 ~~of this Part~~;~~.~~

5) Determining if a medical event, as described in Section 335.1080, has occurred;

6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented; and

7) Determining, for administrations of I-131 in quantities greater than 1.11 MBq (30µCi) ~~megabequerel (30 microcuries)~~, the criteria to be used to identify patients required to be tested for pregnancy in accordance with subsection 335.5010(b), including type of pregnancy testing permitted, time in advance of I-131 administration in which the tests shall be conducted, age range of patients to be tested, and criteria a physician may use to determine that a patient is not capable of childbirth.

c) A licensee shall retain a copy of the procedures required by subsection (a) ~~of this Section~~ for the duration of the license.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

SUBPART C: GENERAL TECHNICAL REQUIREMENTS

Section 335.2010 Possession, Use and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material

a) For ~~licensees performing~~ direct measurements performed in accordance with Section 335.2030, the licensee shall possess and use ~~appropriate~~ instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject~~radioactivity of radiopharmaceuticals~~.

b) A licensee shall calibrate the instrumentation required in subsection (a) ~~Perform tests on each instrument for constancy, accuracy, linearity and geometry dependence,~~ in accordance with nationally recognized standards or the manufacturer's instructions.

c) A licensee shall maintain a record of instrument calibrations required by subsection (b) ~~of this Section~~ for 5 years. The records shall include the model and serial number of the instrument, the date of the calibration, the results of the calibration, the name of the individual who performed the calibration and a copy of the national standard or manufacturer's instructions used to perform the calibration.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

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Section 335.2040 Authorization for Calibration, Transmission, Attenuation Correction and Reference Sources

Any person authorized by Section 335.30 ~~of this Part~~ for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration, transmission, attenuation correction and reference use.~~:~~ Reference sources containing radioactive material authorized under this Part shall not be used for medical use except in accordance with the requirements in Section 335.6010. Sealed sources shall not be combined (i.e. bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this Section. Sealed sources are authorized as follows:

a) Sealed sources not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Section 335.30 ~~of this Part~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations.

b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations ~~of this Part~~, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

c) Any radioactive material with a half-life not greater than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

d) Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCi) or 1000 times the quantities in Appendix B of 32 Ill. Adm. Code 330.

e) Technetium-99m in amounts as needed.

f) Yttrium-90 in individual amounts not to exceed 4.6 GBq (125 mCi).

g) Gadolinium-153 in individual amounts not to exceed 22.2 GBq (600 mCi).

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.2080 Monitoring for Contamination and Ambient Radiation Dose Rate

a) In addition to the monitoring required by 32 Ill. Adm. Code 340, the licensee shall measure~~monitor~~ with a radiation detection survey instrument ~~capable of detecting dose rates over the range 1 mSv(100 mrem) per hour to 500 mSv (50 mrem) per~~

~~hour~~ all areas where unsealed radioactive material was~~liquid radiopharmaceuticals were~~ prepared for use or administered at the end of use each day~~ of use~~. However, the licensee does not need to perform the monitoring required by this Section in areas where patients or human research subjects are confined until release~~when they cannot be released~~ under Section 335.2110~~ of this Part~~. The instrument shall be operable and calibrated in accordance with the requirements of 32 Ill. Adm. Code 340.510(b) and (c).

b) At least once each week, a licensee shall measure with a radiation detection survey~~measurement~~ instrument~~ capable of measuring dose rates over the range 10mSv(1 mrem) per hour to 10 mSv (1 rem) per hour~~ all areas where radiopharmaceuticals or radioactive wastes are stored to ensure compliance with 32 Ill. Adm. Code 340.210 and 340.310. The instrument shall be operable and calibrated in accordance with the requirements of 32 Ill. Adm. Code 340.510(b) and (c).

c) At least once each week, a licensee shall measure for removable contamination in all areas where unsealed radioactive materials are prepared for use, administered or stored.

d) A licensee shall conduct the measurements required by subsections (b) and (c)~~ of this Section~~ in a manner that permits detection of both external exposure rates and removable contamination that would give rise to exposures in excess of the limits specified in 32 Ill. Adm. Code 340.210 and 340.310~~on each wipe sample of 2000 dpm per 100 square centimeters of surface area~~.

e) A licensee shall retain a record of each survey~~all monitoring and surveys~~ required by this Section for 5 years. The record shall include the monitoring date, a description~~sketch~~ of each area monitored, the measurement results~~measured dose rate at several points in each area expressed in units, multiples or subunits of sieverts or rem per hour or the removable contamination in each area expressed in units, multiples or subunits of becquerels or curies per 100 square centimeters of surface area or in disintegrations (transformations) per minute per 100 square centimeters of surface area~~, the manufacturer, model and serial number of the instruments,~~instrument used to perform the monitoring or analyze the samples~~ and the identity of the individual who performed the monitoring.

AGENCY NOTE: For the purposes of this Section, 2000 dpm (disintegrations per minute) per 100 square centimeters of surface area may be utilized as a sufficiently sensitive detection limit for removable contamination unless the licensee has developed alternate removable contamination limits which take into consideration the unsealed radionuclides in use, their respective contribution to the dose limits in 32 Ill. Adm. Code 340.210 and 340.310, and the detection capability of the radiation detection survey

instruments in use. Measurement of removable contamination shall only be performed with a survey instrument, in lieu of wipes, if the instrument is sufficiently sensitive to detect the contamination at the limits specified in this Section~~A detection instrument means an uncompensated Geiger Mueller type instrument. A measurement instrument means an ion chamber or compensated Geiger Mueller instrument~~.
(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.2110 Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material

a) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem) following assessment of the patient's medical, living and working conditions.

AGENCY NOTE: NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," published September 2019~~October 2002~~, exclusive of subsequent amendments or editions, describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

b) If the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem), the licensee shall provide the released individual and, as determined appropriate by the authorized physician user, the individual's spouse, parent, guardian or other primary caregiver with verbal and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If the total effective dose equivalent to a minor, pregnant individual or nursing infant or child could exceed 1 mSv (0.1 rem), assuming there were no interruptions of breast-feeding, the instructions shall also include:

1) Guidance on the interruption or discontinuation of breast-feeding;

2) Guidance on minimizing close or extended contact; and

3) Information on the potential consequences, if any, of failure to follow the guidance.

c) Release of the patient pursuant to this Section shall be approved by an authorized physician user who is approved for the applicable use of radioactive material under Subpart F or H. The authorized user physician shall state in writing that he or she is satisfied that patient compliance with necessary instructions is likely and that the patient is suitable for release.

d) A licensee shall retain a record for 5 years after the release of the individual for the following:

1) The basis for authorizing the release of an individual in accordance with subsections (a) and (b) of this Section to include the assessment and evaluation criteria for the patient's medical, living and working conditions, activities of radioactive material used (i.e., retained or administered activity), occupancy factors, biological or effective half-life of radioactive material, shielding by tissue, and means of estimating doses to any other individual and the physicians.

2) The instructions for each patient required by subsection (b) of this Section.

3) The physician's certification for patient release required by subsection (c) of this Section.

(Source: Amended at 45 Ill. Reg. ____, effective _____)

Section 335.2140 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (Emerging Technologies)

A licensee may use radioactive material or a radiation source that is not specifically addressed in Subparts D through I ~~of this Part~~, or if the use is inconsistent with those Subparts, if:

a) The licensee has submitted the information required by 32 Ill. Adm. Code 330.250 and any other necessary information consistent with 32 Ill. Adm. Code 330;

b) The application contains at least the following:

1) A request signed by management that is consistent with the requirements of 32 Ill. Adm. Code 340.310(b);

2) A description of:

A) The facilities, with a diagram;

B) The necessary equipment and its calibration or maintenance; and

C) Training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officers, authorized users, ~~and~~

authorized medical physicists, and ophthalmic physicists, if not already previously submitted;

3) Procedures, as applicable, that describe:

A) The radionuclide, form and activity;

B) The expected levels of contamination and the procedures to control them;

C) The general safety precautions;

D) The safety instructions to be provided to staff that are specific to the proposed use; and

E) The methodology for measurement of dosages or doses to be administered to patients or human research subjects;

4) If applicable, a description of the sealed source and/or device as per 32 Ill. Adm. Code 330.280(i) and (k), as applicable, or, alternately, identification of the product in the Sealed Source and Device Registry.

c) In addition to the requirements in subsection (b)(2) ~~of this Section~~, an application for a license or amendment for medical use of radioactive material as described in this Section shall also include information regarding any ~~radiation safety~~ aspects of the medical use of radioactive~~the~~ material that are applicable to radiation safety that is not addressed in Subparts A through C ~~of this Part~~.

d) The applicant or licensee has provided any other information requested by the Agency in its review of the application.

e) The licensee has received written approval from the Agency in the form of a license amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the safe use of the material.

AGENCY NOTE: The FDA accepted protocols may be submitted as partial application towards the information requested in this Section.
(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.2150 Additional Technical Requirements for Intravascular Brachytherapy Units

In addition to other provisions required by this Part, the licensee authorized to use an intravascular brachytherapy unit for medical use shall:

a) Have a treatment team consisting of, at a minimum, an interventional cardiologist, an authorized user and an authorized medical physicist and that, at a minimum, an interventional cardiologist and an authorized user will be physically present in the treatment suite during all radioactive procedures.

AGENCY NOTE: The requirements of 32 Ill. Adm. Code 401 regarding radiation therapists must also be met.

b) Independently verify source strength and uniformity. Dwell time at the treatment location must be monitored and recorded. Source uniformity or strength must not differ by more that 10 percent of the expected values.

c) For devices requiring additional shielding, demonstrate compliance with 32 Ill. Adm. Code 340.210 and 340.310 requirements.

d) Inspect sealed sources, source trains or ribbons after each use and ensure sources are removed from service at intervals established by the manufacturer (i.e., confirm that source trains will not be used after the "use by" date, at intervals not to exceed 2 months from the date of shipment, or when evidence of degradation is observed, whichever comes first).

e) Inspect and service devices containing sealed sources at intervals established by the manufacturer, and ensure that maintenance and repair of the device is performed only by the manufacturer or persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such service.

f) Prohibit cuts, alterations or splicing of the sealed sources, source trains or ribbons, except in situations involving an emergency where the source wire cannot be returned to its normal safe position. If such cuts, alterations or splicing are~~is~~ necessary, notification in accordance with Section 335.1080 or 32 Ill. Adm. Code 340.1220 shall be made to the Agency.

g) Use only manufacturer provided inducer sheaths, catheters and accessories to ensure their demonstrated equivalents will be used with the devices.

h) Ensure the daily operational checks will be performed prior to patient treatment. At a minimum, they should include position verification, source uniformity, dwell time function, indicator lamps and other status/operational displays, and visual

inspection for integrity of all applicators and catheters to be used for the treatment.

i) Perform tests following source or device exchange in accordance with the manufacturer's instruction manual for:

1) Timer accuracy/constancy, if appropriate;

2) Calibration of the source output following the manufacturer's instructions; and

3) Interlock/interrupt checks (i.e., interrupt test, cartridge lock test, emergency retraction test and catheter connection test), if appropriate.

j) The licensee shall retain a record of each item in subsections (b), (d), (e), (h) and (i) for intravascular brachytherapy units for 5 years. The records shall include:

1) The date of the verification, inspection or check.

2) The manufacturer's name, model and serial number of the intravascular brachytherapy unit.

3) Results of the verification, inspection or check.

4) Notations indicating the operability of each component.

5) The identity of the individual who performed the check.

(Source: Added at 45 Ill. Reg. _____, effective _____)

SUBPART E: UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED

Section 335.4020 Permissible Concentrations of Molybdenum-99, Strontium-82 and Strontium-85

a) A licensee shall not administer to humans a radiopharmaceutical that contains more than:

1) 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15µCi of molybdenum-99 per mCi of technetium-99m);

2) 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-82 per mCi of rubidium-82); or

3) 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of strontium-85 per mCi of rubidium-82.

b) To demonstrate compliance with subsection (a) ~~of this Section~~, a licensee shall measure:

1) The concentration of molybdenum-99 in each ~~the first~~ eluate from~~after receipt of~~ a molybdenum-99/technetium-99m generator; and

2) The concentration of strontium-82 and strontium-85 before~~for~~ the first patient use of the day on each day that a strontium-82/rubidium-82 generator is used.

c) A licensee shall maintain a record of the concentration tests required by subsection (b) ~~of this Section~~ for 5 years. The record shall include for each measurement, the time and date of the measurement, the name of the individual who made the measurement and, for the corresponding measurement in subsection (b) ~~of this Section~~:

1) The ratio of the measure expressed as kBq of molybdenum per MBq of technetium-99m (or µCi of molybdenum per mCi of technetium); or

2) The ratios of the measures expressed as kBq of strontium-82 per MBq of rubidium-82 and kBq of strontium-85 per MBq of rubidium-82 (or µCi of strontium per mCi of rubidium).

d) A licensee shall notify the Agency and the distributor of the generator for~~report immediately to the Agency~~ each occurrence of a concentration exceeding the limits specified in subsection (a) ~~of this Section~~ as follows:~~.~~

1) Notification by telephone within 7 days after the discovery that an eluate exceeded the permissible concentration. The notification shall include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

2) By an appropriate method listed in 32 Ill. Adm. Code 310.110, the licensee shall submit a written report to the Agency within 30 days after discovery that an eluate exceeded the permissible concentration at the

time of generator elution. The written report shall include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subsection (d)(1).

(Source: Amended at 45 Ill. Reg. _____, effective _____)

SUBPART F: UNSEALED RADIOACTIVE MATERIAL WRITTEN DIRECTIVE REQUIRED

Section 335.5010 Use of Unsealed Radioactive Material for Which a Written Directive is Required

a) A licensee may use any unsealed radioactive material identified in subsection 335.9050(b)(2)(F) prepared for medical use and for which a written directive is required that is:

1) Obtained from a person specified in Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements;

2) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 335.9040, ~~or a combination of Sections~~ 335.9050, ~~and 335.9040(c)(1)(B)(vii)~~ or an individual under the supervision of either as specified in Section 335.1050; or

3) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a protocol accepted by FDA; or

4) Prepared by the licensee for use in research in accordance with an application or a protocol accepted by FDA.

b) Prior to any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131 to a patient~~female~~ capable of childbirth, the licensee shall conduct a pregnancy test and obtain those results to determine pregnancy. If the delay caused by conducting a pregnancy test would jeopardize the patient's health, the test may be forgone provided that action is noted by the authorized user on the written directive required by Section 335.1110. The written directive must also

indicate the patient was informed of the decision to forego the pregnancy test or the reason for omission of the patient notification. Nothing in this Section relieves the licensee from meeting the requirements of Section 335.1100 regarding reporting of exposures to a fetus/embryo.

c) Records of the pregnancy test in subsection (b) shall contain the patient's name, identification number if one has been assigned, the type of test performed, results of the test, the date of the test, date the results became available if different from the test date, and identity of the licensee's staff interpretingadministering the test or, as applicable, the determination by a physician that pregnancy test was not required.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

SUBPART G: SEALED SOURCES FOR DIAGNOSIS

Section 335.6010 Use of Sealed Sources for Diagnosis

A licensee shall use only sealed sources for diagnostic medical uses that are:

a) Obtained from a person specified in Section 335.35335.30 of this Part, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

b) Approved and used in accordance with the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registryand the manufacturer's instruction manual.

c) A licensee shall only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

d) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Section 335.35 are met.

SECOND NOTICE CHANGES
32 ILL. ADM. CODE 335

(Source: Amended at 45 Ill. Reg. _____, effective _____)

SUBPART H: MANUAL BRACHYTHERAPY

Section 335.7010 Use of Sealed Sources for ~~Manual~~ Brachytherapy

A licensee shall use only brachytherapy sources for therapeutic medical uses:

a) That are:

1) Obtained from a person specified in Section 335.35~~335.30 of this Part~~, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; and

2) Approved in~~and used in accordance with~~ the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry~~and the manufacturer's instruction manual~~; or

b) That are used in research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration ~~protocol accepted by the FDA~~ provided the requirements of Section 335.35~~335.30 of this Part~~ are met.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.7070 Calibration Measurements of Brachytherapy Sources

a) Before the first medical use of a brachytherapy source ~~on or after October 24, 2006~~, a licensee shall have:

1) Determined the source output or activity using a dosimetry system that meets the requirements of subsection 335.8080(a)~~Section 335.8080 of this Part~~;

2) Determined source positioning accuracy within applicators; and

3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subsections (a)(1) and (a)(2) ~~of this~~

~~Section~~. Copies of these protocols shall be maintained on file by the licensee for 5 years after the discontinuation of use of brachytherapy sources.

b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine or other calibration laboratory approved by the Agency that are made in accordance with subsection (a) ~~of this Section~~.

c) A licensee shall mathematically correct the outputs or activities determined in subsection (a) ~~of this Section~~ for physical decay at intervals consistent with 1 percent physical decay.

d) A licensee shall maintain a record of the calibrations of brachytherapy sources required by this Section for 5 years after the last use of the source. The record shall~~must~~ include the:

1) Date~~The date~~ of the calibration;

2) Manufacturer's~~The manufacturer's~~ name, model number, and serial number for the source, and the instruments used to calibrate the source;

3) Source~~The source~~ output or activity;

4) Source~~The source~~ positioning accuracy within the applicators; and

5) Name of the individual, source manufacturer, or the calibration laboratory that performed the calibration.~~The signature of the authorized medical physicist~~.

(Source: Added at 45 Ill. Reg. _____, effective _____)

Section 335.7100 Strontium-90 Sources for Ophthalmic Treatments

Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection (c) are performed by either:

a) An authorized medical physicist; or

b) An individual who:

1) is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, U.S. Nuclear Regulatory Commission, or

Agreement State; a permit issued by the Agency, U.S. Nuclear Regulatory Commission, or Agreement State broad scope medical use licensee; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or permit issued by a U.S. Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

2) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

3) has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4) Has documented training in:

A) The creation, modification, and completion of written directives;

B) Procedures for administrations requiring a written directive; and

C) Performing the calibration measurements of brachytherapy sources as detailed in Section 335.7070.

c) The individuals who are identified in subsections (a) and (b) shall:

1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under Section 335.7070; and

2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures shall include the frequencies that the individual meeting the requirements in subsection (a) or (b) will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

d) Licensees must retain a record of the activity of each strontium-90 source. The record shall include:

1) The date and initial activity of the source as determined under Section 335.7070; and

2) For each decay calculation, the date and the source activity as determined under this section.

(Source: Added at 45 Ill. Reg. _____, effective _____)

SUBPART I: REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

Section 335.8010 Use of a Sealed Source in Remote Afterloader Units, ~~Intravascular Brachytherapy Units,~~ Teletherapy Units or Gamma Stereotactic Radiosurgery Units

a) A licensee shall only use sealed sources ~~in remote afterloader units, intravascular brachytherapy units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses that are~~:

1~~a~~) Obtained from a person specified in Section 335.35~~335.30 of this Part~~, or equivalent U.S. Nuclear Regulatory Commission~~,~~ or Agreement State ~~or Licensing State~~ requirements; or

2~~b~~) Approved and as provided for in ~~used in accordance with~~ the Sealed Source and Device Registry, in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses ~~and the manufacturer's instruction manual~~; or

3~~c~~) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units~~Used in research~~ in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration~~FDA~~, provided the requirements of Section 335.35~~335.30 of this Part~~ are met.

b) A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with

radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Section 335.35 are met.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.8040 Safety Procedures and Instructions for Remote Afterloader Units, ~~Intravascular Brachytherapy Units,~~ Teletherapy Units and Gamma Stereotactic Radiosurgery Units

a) A licensee using sealed sources in remote afterloader units, ~~intravascular brachytherapy units,~~ teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses shall:

1) Secure the unit, the console, the console keys and the treatment room when not in use or unattended, if applicable;

2) Permit only individuals approved by the authorized user, Radiation Safety Officer or authorized medical physicist to be present in the treatment room during treatment or emergencies with the sources;

3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

4) Develop, implement and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sources in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures shall include:

A) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

B) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

C) The names and telephone numbers of the authorized users, the authorized medical physicist and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

b) A copy of the procedures required by subsection (a)(4) ~~of this Section~~ and the manufacturer's instruction manual shall be physically located at the unit console.

c) A licensee shall post instructions at the unit console to inform the operator of:

1) The procedures located there as required by subsection (b) ~~of this Section~~; and

2) The names and telephone numbers of the authorized users, the authorized medical physicist and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

d) Operational and Safety Training:

1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, the licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2) Operational and safety instructions are provided, initially and at least to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in:

A) The procedures identified in subsection (a)(4); and

B) The operating procedures for the unit.

~~A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:~~

~~1) The procedures identified in subsection (a)(4) of this Section; and~~

~~2) The operating procedures for the unit.~~ .

e) A licensee shall ensure that operators, authorized medical physicists and authorized users participate in drills of the emergency procedures, initially and at least annually.

f) A licensee shall retain a record of the instruction required by subsection (d) ~~of this Section~~. The record shall be retained for five years and include a list of the topics covered, the date of the instruction, the names of the attendees and the names of the individuals who provided instruction.

g) A licensee shall retain a copy of the procedures required by subsections (a)(4) and (d)(2)(B) ~~of this Section~~ until the licensee no longer possesses the remote afterloader, intravascular brachytherapy unit, teletherapy unit or gamma stereotactic radiosurgery unit.

h) A licensee shall maintain a copy of the record documenting results of the drills of emergency procedures required by subsection (e) ~~of this Section~~ for 5 years.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.8150 Full-Inspection Servicing~~5-Year Inspection~~ for Teletherapy and Gamma Stereotactic Radiosurgery Units

a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not~~or at intervals not to~~ exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit~~, whichever comes first, to assure proper functioning of the source exposure mechanism~~.

b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State ~~or a Licensing State~~.

c) A licensee shall maintain a record of the inspection and servicing~~5-year inspections~~ for teletherapy and gamma stereotactic radiosurgery units required by this Section for the duration of use of the unit.

d) The record shall~~must~~ contain:

1) The inspector's radioactive materials license number;

2) The date of the inspection;

3) The manufacturer's name and model number and serial number of both the treatment unit and source;

4) A list of components inspected and serviced~~, services~~ and the type of service; and

5) The signature of the inspector.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.8220 Additional Technical Requirements for Intravascular Brachytherapy Units (Repealed)

~~In addition to other provisions required by this Part, the licensee authorized to use an intravascular brachytherapy unit for medical use shall:~~

~~a) Have a treatment team consisting of, at a minimum, an interventional cardiologist, an authorized user and an authorized medical physicist and that, at a minimum, an interventional cardiologist and an authorized user will be physically present in the treatment suite during all radioactive procedures.~~

~~AGENCY NOTE: The requirements of 32 Ill. Adm. Code 401 regarding radiation therapists must also be met.~~

~~b) Independently verify source strength and uniformity. Dwell time at the treatment location must be monitored and recorded. Source uniformity or strength must not differ by more that 10 percent of the expected values.~~

~~c) For devices requiring additional shielding, demonstrate compliance with 32 Ill. Adm. Code 340.210 and 340.310 requirements.~~

~~d) Inspect sealed sources, source trains or ribbons after each use and ensure sources are removed from service at intervals established by the manufacturer (i.e., confirm that source trains will not be used after the "use by" date, at intervals not to exceed 2 months from the date of shipment, or when evidence of degradation is observed, whichever comes first).~~

~~e) Inspect and service devices containing sealed sources at intervals established by the manufacturer, and ensure that maintenance and repair of the device is performed only by the manufacturer or persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such service.~~

~~f) Prohibit cuts, alterations or splicing of the sealed sources, source trains or ribbons, except in situations involving an emergency where the source wire cannot be returned to its normal safe position. If such cuts, alterations or splicing is~~

~~necessary, notification in accordance with Section 335.1080 of this Part or 32 Ill. Adm. Code 340.1220 must be made to the Agency.~~

~~g) Use only manufacturer provided inducer sheaths, catheters and accessories to ensure their demonstrated equivalents will be used with the devices.~~

~~h) Ensure the daily operational checks will be performed prior to patient treatment. At a minimum, they should include position verification, source uniformity, dwell time function, indicator lamps and other status/operational displays, and visual inspection for integrity of all applicators and catheters to be used for the treatment.~~

~~i) Perform tests following source or device exchange in accordance with the manufacturer's instruction manual for:~~

~~1) Timer accuracy/constancy, if appropriate;~~

~~2) Calibration of the source output following the manufacturer's instructions; and~~

~~3) Interlock/interrupt checks (i.e., interrupt test, cartridge lock test, emergency retraction test and catheter connection test), if appropriate.~~

~~j) The licensee shall retain a record of each item in subsections (b), (d), (e), (h) and (i) of this Section for intravascular brachytherapy units for 5 years. The records must include:~~

~~1) The date of the verification, inspection or check.~~

~~2) The manufacturer's name, model and serial number of the intravascular brachytherapy unit.~~

~~3) Results of the verification, inspection or check.~~

~~4) Notations indicating the operability of each component.~~

~~5) The signature of the individual who performed the check.~~

(Source: Repealed at 45 Ill. Reg. _____, effective _____)

Section 335.8230 Therapy-related Computer Systems for Remote Afterloader Units, ~~Intravascular Brachytherapy Units,~~ Teletherapy Units and Gamma Stereotactic Units

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

a) The source-specific input parameters required by the dose calculation algorithm;

b) The accuracy of dose, dwell time and treatment time calculations at representative points;

c) The accuracy of isodose plots and graphic displays;

d) The accuracy of the software used to determine sealed source positions from radiographic images; and

e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS

Section 335.9010 Training for Radiation Safety Officer and Associate Radiation Safety Officer

Except as provided in Section 335.9160, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer under the requirement in subsection 335.1040(b) to be an individual who:

a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements ~~has obtained the attestation and training~~ described in subsection (f)~~subsections (e) and (f) of this Section~~. To have its certification process ~~be~~ recognized, a specialty board shall require all candidates for certification to meet the following requirements:

1) The candidate shall:

A) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

B) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

C) Pass an examination administered by diplomates~~diplomate~~ of the specialty board that evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry; or

2) The candidate shall:

A) Hold a master's or doctorate degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

B) Have 2 years of full-time practical training or supervised experience in medical physics:

i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

ii) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in Sections 335.9040, 335.9050 or 335.9160; and

iii) Pass an examination administered by diplomates~~diplomate~~ of the specialty board that evaluates knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b) Has successfully~~obtained the attestation and training described in subsections (e) and (f) of this Section and has~~ completed a structured educational program consisting of both subsections (b)(1) and (b)(2):

1) 200 hours of classroom and laboratory training in the following areas:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Radiation biology; and

E) Radiation dosimetry; and

2) One~~1~~ year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license or permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar types and uses of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license or a permit issued by a master material licensee. The full-time radiation safety experience shall involve the following ~~involving the following~~:

A) Shipping, receiving and performing related radiation monitoring;

B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, instruments used to measure radionuclides and survey meters;

C) Securing and controlling radioactive material;

D) Using administrative controls to avoid mistakes in the administration of radioactive material;

E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

F) Using emergency procedures to control radioactive material;

G) Disposing of radioactive material; and~~or~~

3) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer, that the

individual has satisfactorily completed the requirements in subsections (b)(1), (b)(2) and (f) and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

c) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency under subsection 335.9150(a) or the U.S. Nuclear Regulatory Commission or an Agreement State and has experience with the~~in~~ radiation safety aspects of ~~for~~ similar types of use of radioactive material for which approval of the individual as Radiation Safety Officer or Associate Radiation Safety Officer is sought and meets the requirements in subsection (f)~~who has obtained the attestation and training described in subsections (e) and (f) of this Section~~; or

d) Is an authorized user or authorized medical physicist identified on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State licensee of broad scope, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee; ~~the licensee's license and~~ has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as~~has~~ Radiation Safety Officer or an Associate Radiation Safety Officer; and meets the requirements in subsection (f); or.~~responsibilities; and~~

e) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license. The individual must also meet the requirements in paragraph (f) of this Section.

~~e) Has obtained written attestation signed by a preceptor Radiation Safety Officer, that the individual has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

~~1) Has satisfactorily completed the requirements described in:~~

~~A) Subsection (f) of this Section and subsections (a)(1)(A) and (B) of this Section; or~~

~~B) Subsection (f) of this Section and subsections (a)(2)(A) and (B) of this Section; or~~

~~C)~~ ~~Subsections (b) and (f) of this Section; or~~

~~2)~~ ~~Meets the criteria of subsection (c) or (d) of this Section and has received the training required by subsection (f) of this Section.~~

f) Has received training in radiation safety, regulatory issues and emergency procedures for the types of use for which approval is sought. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval ~~is sought~~.

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State will be posted on the NRC's website.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9030 Training for Uptake, Dilution or Excretion Studies

Except as provided in Section 335.9160, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.3010 not requiring a written directive to be a physician who:

a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State ~~and who has obtained the attestation required by subsection (d) of this Section~~. To have its certification process~~be~~ recognized, a specialty board shall require all candidates for certification to meet the following requirements:

1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies as described in subsections (c)(1) and (2) ~~of this Section~~; and

2) Pass an examination administered by diplomates~~diplomate~~ of the specialty board, that evaluates knowledge and competence in radiation safety, radionuclide handling and quality control; or

b) Is an authorized user who meets the requirements of Section 335.9040 or 335.9050 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

c) Has successfully ~~obtained the attestation described in subsection (d) of this Section and has~~ completed a structured educational program consisting of:

1) 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies. The classroom and laboratory training shall include, at a minimum:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9040, 335.9050 or 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements involving:

A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation monitoring;

B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

F) Administering dosages of radioactive drugs to patients or human research subjects; and.

3) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (c) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized by Section 335.3010. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section or Section 335.9040, 335.9050 or 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Sections 335.9040, 335.9050 or 335.9160, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and work experience specified in subsections (c)(1) and (c)(2).

d) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) or (c) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the uses authorized by Section 335.3010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section or Section 335.9040, 335.9050 or 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

SECOND NOTICE CHANGES
32 ILL. ADM. CODE 335

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9040 Training for Imaging and Localization Studies

Except as provided in Section 335.9160, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.4010 not requiring a written directive to be a physician who:

a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State ~~and who has obtained the attestation described in subsection (d) of this Section~~. To have its certification process~~be~~ recognized, a specialty board shall require all candidates for certification to meet the following requirements:

1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in subsection (c) ~~of this Section~~; and

2) Pass an examination administered by diplomates~~diplomate~~ of the specialty board, that evaluates knowledge and competence in radiation safety, radionuclide handling and quality control; or

b) Is an authorized user who meets the requirements of Section 335.9050 and meets the requirements in subsection (c)(1)(B)(vii)~~(c)(2)(G) of this Section~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

c) Has successfully completed ~~obtained the attestation described in subsection (d) of this Section and has completed a structured educational program consisting of~~ 700 hours of training and experience, including 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. ~~The training and experience shall include at a minimum~~:

1) The training and experience shall include at a minimum:

A) Classroom and laboratory training in the following areas:

i) Radiation physics and instrumentation;

ii) Radiation protection;

iii) Mathematics pertaining to the use and measurement of radioactivity;

iv) Chemistry of radioactive material for medical use;

v) Radiation biology; and

B) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050, together with subsection (c)(1)(B)(vii), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:

i) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation monitoring;

ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;

iii) Calculating, measuring and safely preparing patient or human research subject dosages;

iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

vi) Administering dosages of radioactive drugs to patients or human research subjects;

vii) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring, and testing the eluate for radionuclidic purity and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2) Has obtained written attestation that the individual has satisfactorily completed the requirements described in subsection (c)(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Sections 335.3010 and 335.4010. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050 together with subsection (c)(1)(B)(vii) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050, together with subsection (c)(1)(B)(vii) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsections (c) and (c)(1).

~~Classroom and laboratory training in the following areas:~~

~~A) Radiation physics and instrumentation;~~

~~B) Radiation protection;~~

~~C) Mathematics pertaining to the use and measurement of radioactivity;~~

~~D) Chemistry of radioactive material for medical use;~~

~~E) Radiation biology; and~~

~~2) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050 together with subsection (c)(2)(G) of this Section, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving:~~

~~A) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation monitoring;~~

B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages of radioactive drugs to patients or human research subjects;

G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring, and testing the eluate for radionuclidic purity and processing the eluate with reagent kits to prepare labeled radioactive drugs.

d) Has obtained written attestation that the individual has satisfactorily completed the requirements described in subsection (a)(1), (b) or (c) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Sections 335.3010 and 335.4010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9160 or Section 335.9050 together with subsection (c)(2)(G) of this Section or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9050 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required

Except as provided in Sections 335.9060, 335.9070, 335.9080 and 335.9160, a licensee shall require the authorized user of unsealed radioactive material for the uses authorized under Section 335.5010 to be a physician who:

a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in~~has the work experience required by~~ subsection (b)(2)(F) ~~of this Section and has obtained the attestation described in subsection (c) of this Section~~. To be recognized, a specialty board shall require all candidates for certification to meet the following requirements:

1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in subsection (b)(1) through (b)(2)(E) ~~of this Section~~. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education ~~or~~, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training~~Committee on Post-Graduate Training~~ of the American Osteopathic Association;

2) Pass an examination administered by diplomates~~diplomate~~ of the specialty board that evaluates knowledge and competence in radiation safety, radionuclide handling, quality assurance and clinical use of unsealed radioactive materials; or

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

b) Has successfully ~~obtained the attestation described in subsection (c) of this Section and has~~ completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include:

1) Classroom and laboratory training in the following areas:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in subsection (b) ~~of this Section~~ shall have experience in administering dosages in the same dosage category or categories (i.e., subsection (b)(2)(F) ~~of this Section~~) as the individual requesting authorized user status. The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation monitoring;

B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

i) Oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131 for which a written directive is required;

ii) Oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131;

AGENCY NOTE: Experience with at least 3 cases described in subsection (b)(2)(F)(ii) ~~of this Section~~ satisfies the requirement in subsection (b)(2)(F)(i) ~~of this Section~~.

iii) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or ~~beta emitter or a photon-emitting radionuclide with a~~ photon energy of less than 150 keV, for which a written directive is required; and~~or~~

3) Written attestation that the individual has satisfactorily completed the requirements in subsections (b)(1) and (b)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Section 335.5010 for which the individual is requesting authorized user status. The attestation shall be signed by either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsections (b)(1) and (b)(2).

~~iv) Parenteral administration of any other radionuclide for which a written directive is required.~~

~~c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (b) of this Section or subsection (a)(1) of this Section together with subsection (b)(2)(F) of this Section and has achieved a level of competency sufficient to function independently as~~

~~an authorized user for the medical uses authorized under Section 335.5010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in subsection (b) of this Section shall have experience in administering dosages in the same dosage category or categories (i.e., subsection (b)(2)(F) of this Section) as the individual requesting authorized user status.~~

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9060 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 GBq (33 mCi)

Except as provided in Section 335.9160, the licensee shall require the authorized user for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi) to be a physician who:

a) Is certified by a medical specialty board whose certification process includes all of the requirements in subsections (c)(1) and (c)(2)~~subsection (c) of this Section~~ and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State ~~and who has obtained the attestation described in subsection (d) of this Section~~; or

b Is an authorized user who meets the requirements of Section 335.9070 or Section 335.9050 for the uses identified in subsection 335.9050(b)(2)(F)(i) or (ii) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

c) Has successfully completed a structured educational program consisting of~~obtained the attestation described in subsection (d) of this Section and has~~:

1) ~~Successfully completed~~ 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include :

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience under the supervision of an authorized user who meets the requirements of this Section, Section 335.9050, 335.9070, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements of subsection 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(i) or (ii). The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation monitoring;

B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages to patients or human research subjects and shall include at least 3 cases involving the oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131; and.

3) Written attestation that the individual has satisfactorily completed the requirements in subsections (c)(1) and (c)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 GBq (33 mCi) of sodium iodide I-131 for medical uses authorized under Section 335.5010. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9070, 335.9160 or

equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(i) or (ii); or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Section 335.9050, 335.9070, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(i) or (ii) and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsections (c)(1) and (c)(2).

~~d) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a) or (c) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.5010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9070, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in Section 335.9050(b)shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(i) or (ii).~~

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9070 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 GBq (33 mCi)

Except as provided in Section 335.9160, the licensee shall require the authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi) to be a physician who:

a) Is certified by a medical specialty board whose certification process includes all of the requirements in subsections (c)(1) and (c)(2)~~subsection (c) of this Section~~ and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State ~~and who has obtained the attestation described in subsection (d) of this Section~~; or

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

b) Is an authorized user who meets the requirements of Section 335.9050 for the uses identified in subsection 335.9050(b)(2)(F)(ii), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

c) Has successfully completed a structured educational program consisting of~~obtained the attestation described in subsection (d) of this Section and has~~:

1) ~~Successfully completed~~ 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include :

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use;

E) Radiation biology; and

2) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9050, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements of Section 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(ii). The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation monitoring;

B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

F) Administering dosages to patients or human research subjects and shall include at least 3 cases involving the oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131; and.

3) Written attestation that the individual has satisfactorily completed the requirements in subsections (c)(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 GBq (33 mCi) of sodium iodide I-131 for medical uses authorized under Section 335.5010. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(ii); or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Section 335.9050, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(ii), and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for

Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsections (c)(1) and (c)(2).

d) ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a) or (c) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Section 335.5010. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in Section 335.9050(b) shall have experience in administering the dosages identified in subsection 335.9050(b)(2)(F)(ii).~~

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9080 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive

Except as provided in Section 335.9160, the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

a) Is an authorized user who meets the requirements of Section 335.9050 for a use identified in subsection 335.9050(b)(2)(F)(iii) ~~or (iv)~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

b) Is an authorized user under Section 335.9100 or 335.9140 ~~or 335.9160~~ or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and who meets the requirements in subsection (d) ~~of this Section and has obtained the attestation described in subsection (e) of this Section~~; or

c) Is certified by a medical specialty board whose certification process has been recognized by the Agency under Section 335.9100 or 335.9140 or by the U.S. Nuclear Regulatory Commission or an Agreement State and who meets~~. The individual shall meet~~ the requirements in subsection (d)~~. of this Section and have obtained the attestation described in subsection (e) of this Section; or~~

d) The physician shall have~~Has obtained the attestation described in subsection (e) of this Section and has~~:

1) Successfully completed 80 hours of classroom and laboratory training applicable to parenteral administrations listed in subsection

335.9050(b)(2)(F)(iii)~~administration of radioactive material for which a written directive is required. The training shall apply to any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~. The training shall include:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Chemistry of radioactive material for medical use; and

E) Radiation biology.~~; and~~

2) Work experience under the supervision of an authorized user who meets the requirements in this Section, Section 335.9050, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements in the parenteral administrations listed in subsection 335.9050(b)(2)(F)(iii) ~~administration of radioactive material for which a written directive is required. The experience shall include administration of any beta emitter, any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~. A supervising authorized user who meets the requirements in this Section, Section 335.9050, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status~~as identified in Section 335.9050(b)(2)(F)(iii) or (iv)~~. The work experience shall involve:

A) Ordering, receiving and unpacking radioactive materials safely, and performing the related radiation surveys;

B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

C) Calculating, measuring and safely preparing patient or human research subject dosages;

D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

F) Administering dosages to patients or human research subjects that include at least 3 cases of~~involving~~ the parenteral administrations as specified in subsection 335.9050(b)(2)(F)(iii); and ~~administration of radioactive material for which a written directive is required. This experience shall include administration of any beta emitter, any photon-emitting radionuclide with a photon energy less than 150 keV or at least 3 cases involving the parenteral administration of any other radionuclide for which a written directive is required.~~

3) Obtained written attestation that the individual has satisfactorily completed the requirements in subsections (d)(1) and (d)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in this Section or Section 335.9050, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Section 335.9050, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of

Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsection (d)(1) and (d)(2).

~~e) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (b), (c) or (d) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9050, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in Section 335.9050 shall have experience in administering dosages identified in subsections 335.9050(b)(2)(F)(iii) or (iv).~~

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9100 Training for Use of Manual Brachytherapy Sources

Except as provided in Section 335.9160, the licensee shall require the authorized user of a manual brachytherapy source under the provisions and requirements of Subpart H to be a physician who:

a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State ~~and who has obtained the attestation described in subsection (c) of this Section~~. To have its certification process~~be~~ recognized, a specialty board shall require all candidates for certification to:

1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, ~~or~~ the Royal College of Physicians and Surgeons of Canada, or the Council~~the Committee~~ on Postdoctoral~~Post-Graduate~~ Training of the American Osteopathic Association; and

2) Pass an examination administered by diplomates~~diplomate~~ of the specialty board that evaluates knowledge and competence in radiation safety,

radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy sources; or

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

b) The physician~~Has obtained the attestation described in subsection (c) of this Section and~~ has:

1) Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

A) 200 hours of classroom and laboratory training in the following areas:

i) Radiation physics and instrumentation;

ii) Radiation protection;

iii) Mathematics pertaining to the use and measurement of radioactivity;

iv) Radiation biology; and

B) 500 hours of work experience, ~~at a medical institution~~ under the supervision of an authorized user who meets the requirements in this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, at a medical facility authorized to use radioactive material under Subpart H. The work experience shall include:

i) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation monitoring;

ii) Checking survey instruments for proper operation;

iii) Preparing, implanting and removing brachytherapy sources;

iv) Maintaining running inventories of material on hand;

v) Using administrative controls to prevent medical events involving radioactive material;

vi) Using emergency procedures to control radioactive material; and

2) Completed 3 years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The experience shall be obtained as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council~~the Committee~~ on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (b)(1)(B); and ~~of this Section~~.

3) Obtained written attestation that the individual has satisfactorily completed the requirements in subsections (b)(1) and (b)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources under Subpart H. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Section 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsections (b)(1) and (b)(2).

~~c)~~ ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) or (b) of this Section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources under Subpart H. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.~~

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9120 Training for Ophthalmic Use of Strontium-90

Except as provided in Section 335.9160, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiation therapy to be a physician who:

a) Is an authorized user who meets the requirements of Section 335.9100 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

b) Has ~~obtained the attestation described in subsection (c)of this Section and has~~:

1) Completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiation therapy. The training shall include:

A) Radiation physics and instrumentation;

B) Radiation protection;

C) Mathematics pertaining to the use and measurement of radioactivity;

D) Radiation biology; and

2) Completed clinical training in ophthalmic radiation therapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of 5 individuals~~patients~~. The supervised clinical training shall include:

A) Examination of each individual~~patient~~ to be treated;

B) Calculation of the dose to be administered;

C) Administration of the dose; and

D) Follow-up and review of each individual's~~patient's~~ case history; and~~.~~

3) Obtained written attestation that the individual has satisfactorily completed the requirements in subsections (b)(1) and (b)(2) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9100, 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

~~c)~~ ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (b) of this Section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section, Section 335.9100, 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.~~

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9130 Training for Use of Sealed Sources for Diagnosis

Except as provided in Section 335.9160~~ of this Part~~, the licensee shall require the authorized user of a diagnostic sealed source~~ for diagnostic use in~~ or a device authorized in Section 335.6010~~ of this Part~~ to be a physician, dentist or podiatrist who:

a) Is certified by a specialty board whose certification process includes all of the requirements in subsection (c~~b~~)~~ of this Section~~ and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State~~ or a Licensing State~~; or

b) Is an authorized user for uses listed in Section 335.4010 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

c~~b~~) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:

1) Radiation physics and instrumentation;

2) Radiation protection;

3) Mathematics pertaining to the use and measurement of radioactivity;

4) Radiation biology; and

5) Training in the use of the device for the uses requested; and.

d) Has completed training in the use of the device for the uses requested.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9140 Training for Use of Remote Afterloader Units, ~~Intravascular Brachytherapy Units,~~ Teletherapy Units and Gamma Stereotactic Radiosurgery Units

Except as provided in Section 335.9160, the licensee shall require the authorized user of a sealed source under the provisions and requirements of Subpart I to be a physician who:

a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in~~has obtained the attestation described in subsection (c) of this Section and the training required by~~ subsection (d)~~ of this Section~~. To have its certification process~~be~~ recognized, a specialty board shall require all candidates for certification to:

1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, ~~or~~ the Royal College of Physicians and Surgeons of Canada, or the Council~~the Committee~~ on Postdoctoral~~Post-Graduate~~ Training of the American Osteopathic Association; and

2) Pass an examination administered by diplomates~~diplomate~~ of the specialty board that evaluates knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

b) Has ~~obtained the attestation described in subsection (c) of this Section, the training required by subsection (d) of this Section and has~~:

1) Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

A) 200 hours of classroom and laboratory training in the following areas:

i) Radiation physics and instrumentation;

ii) Radiation protection;

iii) Mathematics pertaining to the use and measurement of radioactivity;

iv) Radiation biology; and

B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this Section, Section 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, at a medical institution that is authorized to use radioactive materials under Subpart I ~~under the supervision of an authorized user who meets the requirements in this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements~~. The work experience shall include:

i) Reviewing full calibration measurements and periodic spot-checks;

ii) Preparing treatment plans and calculating treatment doses and times;

iii) Using administrative controls to prevent a medical event involving the use of radioactive material;

iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

v) Checking and using survey instruments;

vi) Selecting the proper dose and how it is to be administered; and

2) Completed 3 years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements of this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State or requirements. The experience shall be obtained as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council~~the Committee~~ on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (b)(1)(B); and ~~of this Section.~~

3) Obtained written attestation that the individual has satisfactorily completed the requirements in subsections (b)(1), (b)(2), and (c) and is able to independently fulfill the radiation safety-related duties as an authorized user for the type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation shall be obtained from either:

A) A preceptor authorized user who meets the requirements in this Section, Section 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for each type of therapeutic medical unit for which the individual is requesting authorized user status; or

B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, Section 335.9160, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for the types of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in subsections (b)(1) and (b)(2).

~~e)~~ ~~Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (a)(1) and (d) or (b) and (d) of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation shall be signed by a preceptor authorized user who meets the requirements in this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for each type of therapeutic medical unit for which the individual is requesting authorized user status.~~

cd~~)~~) Has received training in device operation, safety procedures and clinical use for the typestype of therapeutic medical unit for which authorization is sought. This training requirement may be met by satisfactory completion of a training program provided by the vendor for new users ~~by the equipment supplier~~ or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

AGENCY NOTE: The term "type of therapeutic medical unit" refers to a type of use identified in this Section. It applies to this Section only. Training for therapeutic medical units is not manufacturer-specific. Training for one brand of therapeutic medical unit is acceptable for another brand of the same type of unit

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9150 Training for Authorized Medical Physicist

Except as provided in Section 335.9160, the licensee shall require the authorized medical physicist to be an individual who:

a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in ~~has obtained the attestation described in subsection (c) of this Section and the training required by~~ subsection (d) ~~of this Section~~. To be recognized, a specialty board shall require all candidates for certification to:

1) Hold a master's degree or doctorate in physics, medical physics, other physical science, engineering or applied mathematics from an accredited college or university;
2) Have 2 years of full-time practical training or supervised experience in medical physics:

A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State; or

B) In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy~~brachytheraphy~~ services under the direction of physicians who meet the requirements for authorized users in Section 335.9100, 335.9140 or 335.9160;

3) Pass an examination administered by diplomates~~diplomate~~ of the specialty board that evaluates knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery; or

AGENCY NOTE: Specialty boards whose certification processes have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the NRC's website.

b) Holds a master's degree or doctorate in physics, medical physics or other physical science, engineering or applied mathematics from an accredited college or university and has~~. Has~~ completed one~~1~~ year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and shall include:

1) Performing sealed source leak tests and inventories;

2) Performing decay corrections;

3) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units and remote afterloading units as applicable;

4) Conducting radiation monitoring around external beam treatment units, stereotactic radiosurgery units and remote afterloading units, as applicable; and

c) Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~subsections (a)(1), (a)(2) and (d) or~~ subsections (b) and (d) of ~~this Section~~ and is able to independently fulfill the radiation safety-related duties ~~has achieved a level of competency sufficient to function independently~~ as an authorized medical physicist for each type of use for which the individual is requesting authorized medical physicist status. The attestation shall be signed by a preceptor authorized medical physicist who meets the requirements of this Section or Section 335.9160 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of use for which the individual is requesting authorized medical physicist status.

d) Has training in the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by an equipment supplier or by training supervised by an authorized medical physicist authorized for the type of use for which the individual is seeking authorization.

(Source: Amended at 45 Ill. Reg. _____, effective _____)

Section 335.9160 Training for Experienced Radiation Safety Officer, Authorized Medical Physicist or Authorized User

a) For experienced Radiation Safety Officers and Authorized Medical Physicists:

1)~~a)~~ An individual identified as a Radiation Safety Officer or an authorized medical physicist on an Agency, U.S. Nuclear Regulatory Commission or Agreement State license or a permit issued by an Agency, U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before January 14, 2022~~October 24, 2007~~ need not comply with the training requirements of Sections 335.9010 and 335.9150, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this subsection shall meet the training requirements in subsections 335.9010(e) and 335.9150(d), as appropriate, for any material or uses for which they were not authorized prior to this date.

2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics, the American Board of Radiology, the American Board of Nuclear Medicine, the American Board of Science in Nuclear Medicine, the Board of Pharmaceutical Specialties in Nuclear Pharmacy, the American Board of Medical Physics in radiation oncology physics, the Royal College of Physicians and Surgeons of Canada in nuclear medicine, the American Osteopathic Board of Radiology, or the American Osteopathic Board of Nuclear Medicine on or before October 24, 2007 need not comply with the training requirements of Section 335.9010 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a U.S. Nuclear Regulatory Commission or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2007.

3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2007 need not comply with the training requirements for an authorized medical physicist described in Section 335.9150, for those materials and uses that these individuals performed on or before October 24, 2007.

b) For physicians, dentists or podiatrists:

1)~~b)~~ Physicians, dentists or podiatrists~~,~~ identified as authorized users for the medical use of radioactive material on a license issued by the Agency, U.S. Nuclear Regulatory Commission or Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, U.S. Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2022~~October 24, 2007~~ who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Sections 335.9030 through 335.9140.

2) Physicians, dentists or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Agency, U.S. Nuclear Regulatory Commission or Agreement State, a permit issued by the U.S. Nuclear Regulatory Commission master licensee, a permit issued by the Agency, U.S. Nuclear Regulatory Commission or

Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2007 need not comply with the training requirements of Sections 335.9030 through 335.9140 for those materials and uses that these individuals performed on or before October 24, 2007 as follows:

A) For uses authorized under Section 335.3010, 335.4010, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2007, in nuclear medicine by the American Board of Nuclear Medicine, diagnostic radiology by the American Board of Radiology, diagnostic radiology or radiology by the American Osteopathic Board of Radiology, nuclear medicine by the Royal College of Physicians and Surgeons of Canada, or the American Osteopathic Board of Nuclear Medicine in nuclear medicine;

B) For uses authorized under Section 335.5010, a physician who was certified on or before October 24, 2007 by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

C) For uses authorized under Sections 335.7010 and 335.8010, a physician who was certified on or before October 24, 2007 in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

D) For uses authorized under Section 335.6010, a physician who was certified on or before October 24, 2007 in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

c) Individuals who are not subject to the training requirements in this Section may serve as preceptors for and supervisors of applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

d) Individuals that qualify under this Section need to comply with Section 335.9180.

(Source: Amended at 45 Ill. Reg. _____, effective _____)